PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 52332AWOM1	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP 03/11662	International filing date *(day/month/year)* 21.10.2003	Priority date *(day/month/year)* 22.10.2002
International Patent Classification (IPC) or both national classification and IPC C07K14/72		
Applicant SCHERING AKTIENGESELLSCHAFT et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

I	☒	Basis of the opinion
II	☐	Priority
III	☒	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	☒	Lack of unity of invention
V	☒	Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	☐	Certain documents cited
VII	☐	Certain defects in the international application
VIII	☐	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
18.02.2004	11.01.2005
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Grosskopf, R Telephone No. +49 89 2399-8714

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP 03/11662

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-49 as originally filed

Sequence listings part of the description, Pages

1-160 as originally filed

Claims, Numbers

1-58 as originally filed

Drawings, Sheets

1/3-3/3 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☒ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☒ furnished subsequently to this Authority in computer readable form.

   ☒ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 1-58

   because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

   ☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 1-58 are so unclear that no meaningful opinion could be formed *(specify)*:

   see separate sheet

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☒ no international search report has been established for the said claims Nos. 36,37,52,55

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees, the applicant has:

   ☐ restricted the claims.

   ☐ paid additional fees.

   ☐ paid additional fees under protest.

   ☐ neither restricted nor paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

☐ complied with.

☐ not complied with for the following reasons:

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

☒ all parts.

☐ the parts relating to claims Nos. .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1
Industrial applicability (IA)	Yes:	Claims	1
	No:	Claims	

2. Citations and explanations

see separate sheet

Ad item III, IV and V:

In principle, the present application is totally non-unitary since the various polypeptides or fragments thereof (most of them have no function at all) from different organisms do not share a common special technical feature (which could only be a common structural feature, i.e. a sequence element) in view of the known sequence of the HE6 and its counterparts in other mammalian species (see D1 and D2; Genomics 55, 296-305 (1999) and EP 0805204).
An explicit lack of unity objection, however, has not been raised during the search and will neither be raised in examination in view of the following considerations.

First, it as mentioned that if such a objection had been raised, the search would have been restricted to SEQ ID NO: 1 (which is certainly not Applicant's desire).

Second, it is impossible to determine the number of potential alleged inventions, especially when taking into account that the claims are not even restricted to the specific sequences but include (undefined) functional variants or "related " sequences having a certain degree of identity. Moreover, the sequences (fragments) of e.g. Claim 1 do not relate to a single defined protein fragment but include all possible three reading frames (which renders the alleged invention completely obscure and potentiates the possible number of fragments).

Thus, and from a different point of view, the present set of claims encompasses an uncountable number of entities, said entities, in principle, correspond to independent claims (even when contained in one claim as alternatives).
This means that in addition to the objection for lack of unity, an objection for lack of clarity has to be raised which renders a complete (and meaningful) search impossible.

Anyhow, as long as the claimed sequences are not limited to those sequences which share a single common special (i.e. novel) sequence element and/or a common special function (which can certainly not be the fact that the "functional" fragments "exhibit a biological activity and/or immunogenicity of the polypeptide from which it is derived"; see page 11, lines 16 to 19 of the description), the above mentioned objections will still apply and, consequently, (in correspondence to the lack of a meaningful search) no meaningful (and complete) examination can be carried out.
In view of these considerations, the present search had to be limited to the complete

protein which, with regard to D1 and D2 is however neither novel nor inventive.
For sake of completeness, it should be mentioned that also no search at all had been be carried out with regard to compounds which are not defined by any structural feature (antagonists, inhibitors etc.) and claims relating to the use of said compounds.